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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,049	07/24/2000	Reinhilde Schoonjans	DECL18.001C1	6634
20995	7590	03/25/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			HELMS, LARRY RONALD	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1642	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/625,049

**Applicant(s)**

SCHOONJANS ET AL.

**Examiner**

Larry R. Helms

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-47, 49, 50 and 61-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 43-47, 49, 50, 61-67 and 69 is/are allowed.
- 6) ☒ Claim(s) 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claim 43, 67, 68 have been amended.  
  
Claim 48 has been canceled.  
  
Claims 43-47, 49-50, 61-69 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains a NEW GROUND of rejection.

### ***Rejections Withdrawn***

4. The rejection of claims 43-50, 61-69 under 35 U.S.C. 102(b) as being anticipated by Harris et al (WO 94/09131, published 4/94) is withdrawn in view of the amendments to the claims.

### ***The following is a NEW GROUND of rejection***

### ***Claim Rejections - 35 USC § 103***

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al (WO 94/09131, published 4/94, PTO-892, paper 23) and further in view of Huston et al (Methods in Enzymology 203: 46-88).

The claim is summarized as a multipurpose heterodimeric antibody comprising CL-VL and CH1-VH further comprising two or more molecules of scFv linked by the N-terminus to the domains.

Harris et al teach molecules with CH1-VH and CL-VL domains associating and each of the domains, CH1 and CL, can have scFv linked to them with a peptide linker (see Figure 8-9, page 7, lines 1-5, page 24-25, page 26, lines 2-15). Harris et al does not teach fusion of the scFv at its N-terminus to the domain. This deficiency is made up for in the teachings of Huston et al.

Huston et al teach scFv fusions and the fusions can be at the N-terminus or the C-terminus (see pages 56-57).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have fused two scFv domains at their N-terminus to either the CH1 or CL domain in a molecule.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have fused two scFv domains at their N-terminus to either the CH1 or CL domain in a molecule because Harris et al teach fusion proteins comprising two scFv fused to a VH-CH1 and VL-CL domain wherein the scFv is fused at the C-terminus to the domains (see Figure 8) and it would have been obvious to fuse the scFv at their N-terminus to the VH-CH1 and VL-CL domain because Huston teach that the effector molecules can be fused at either the N-terminus or C-terminus and still retain function (see page 56-57). Thus, it would have been obvious to fuse the scFv by their N-terminus to the domains of VH-CH1 and VL-CL.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Conclusion***

7. Claims 43-47, 49-50, 61-67, 69 are in condition for allowance.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,


Larry R. Helms Ph.D.

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571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER